K000636

MAY 11 2000

510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
Stryker Trauma Plating System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:

Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677
201-825-4900

Contact Person:

Mary-Catherine Dillon
Regulatory Affairs Team Member

Date Summary Prepared:

February 7, 2000

Device Identification

Proprietary Name:

Stryker Trauma Plating System

Common Name:

Plating System

Classification Name and Reference:

Plate, Fixation, Bone
21 CFR §888.3030

Predicate Device Identification

The Stryker Trauma Plating System is substantially equivalent to the Alphatec Small Fragment System and the Smith and Nephew TC-100™ Screw and Plating System.

Device Description

The Stryker Trauma Plating System consists of a variety of compression plates, cortical and cancellous screws, washers, and K-wires. The plates are either 9mm or 10mm wide, have thickness of 1mm to 3mm, and range in length from 24mm to 390mm. The subject screw components come in thread diameters of 2.7mm, 3.5mm, and 4.0mm. The screws range in length from 10-60mm. All devices in the system are provided non-sterile. The subject device also includes washers and K-wires.

Intended Use

The Stryker Trauma Plating System is indicated for fractures of the metaphysis and/or the diaphysis of the following:

One Third Tubular Plate: fibula, metatarsals, metacarpals
Compression Plate: radius, ulna, distal tibia, fibula, distal humerus, clavicle
Oblique T-Plate: distal radius
T-Plate: distal radius, calcaneus, lateral clavicle
Cloverleaf Plate: proximal humerus, distal tibia
Calcaneal Plate: calcaneus
Reconstructive Plate: humerus, pelvis

Screws are used either to fasten plates or similar devices onto bone, or, as lag screws, to hold together fragments of bone.

Materials

The subject components can be manufactured from either titanium alloy (ASTM 136-92) or stainless steel (ASTM 138 or ASTM 1314).

Statement of Technological Comparison

The subject components of the Stryker Trauma Plating System are substantially equivalent in design, intended use, and material to the predicate devices offered by Alphatec and Smith and Nephew.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2000

Ms. Mary-Catherine Dillon
Regulatory Affairs Team Member
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K000636
Trade Name: Stryker Trauma Plating System
Regulatory Class: II
Product Code: HRS, HWC
Dated: February 10, 2000
Received: February 25, 2000

Dear Ms. Dillon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000636

Device Name: Stryker Trauma Plating System

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachuska
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000636

Prescription Use ✓ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)